



U.S. Department of Justice

United States Attorney
Western District of New York

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PRESS RELEASE

June 8, 2006

**RE: GOVERNMENT MOVES FOR SEIZURE AND FORFEITURE OF
2.7 MILLION DOLLARS OF UNAPPROVED MEDICAL DEVICES**

United States Attorney Terrance P. Flynn announced today the filing, in U.S. District Court for the Western District of New York, of a Complaint seeking the seizure and ultimate forfeiture of numerous medical devices and their component parts. The Complaint alleges that the medical devices and their component parts are in violation of a series of Food And Drug Administration (FDA) statutes in that the devices are both adulterated and misbranded. Chief Judge of the Western District of New York, Richard J. Arcara, has scheduled an initial court conference on the litigation for August 25, 2006 at 9:00 a.m.

The Complaint alleges that between August of 2005 and January of 2006, Universal Academy, Inc., shipped into the United States from Canada over 200,000 units and component parts to a fulfillment business in the Buffalo area. The owner of the property is allegedly a Canadian company called Universal Academy located in Markham, Ontario, and is associated with a Dr. Ho from China. Dr. Ho sold these devices touting miracle cures using his various products. The medical devices, called Dr-Ho's Double Massage and Dr- Ho's Muscle Massage were marketed in the United States. FDA officials have put the retail value of the medical devices in excess of 2.7 million dollars. The complaint seeks the forfeiture and ultimate destruction of the devices.

The devices, components, and accessories, are adulterated under the Federal Food, Drug, and Cosmetic Act (Act) because they are unapproved class III medical devices and they do not meet mandatory performance standards. In addition, the devices are labeled for use to treat serious medical conditions, including diabetic neuropathy,

fibromyalgia, arthritis, migraine headaches, and multiple sclerosis. Since these devices have not been approved by FDA, the safety parameters associated with their use and the efficacy of the devices for use to treat diseases have not been determined. These devices are misbranded because their labeling lacks adequate directions for intended use, they are not labeled prescription use only, and they are not being used by consumers by an order of a licensed practitioner. They are further misbranded because they were manufactured at an unregistered facility.

After the units were assembled in the Buffalo area, they were transferred to another warehouse in Connecticut where they were then shipped to consumers throughout the United States. U.S. Attorney Flynn also noted that the United States Attorney's Office in New Haven, Connecticut, has also filed a civil complaint against approximately \$450,000 worth of Dr-Ho medical devices found there.

The case is being investigated by the Food and Drug Administration, under the direction of Compliance Officer James Kewley and Investigator Michael Charles, both with the FDA's New York District-Buffalo Office. U.S. Attorney Flynn noted that the fulfillment house, GRE Fulfillment, has cooperated fully with the investigation. The case is being prosecuted by Assistant United States Attorney Richard D. Kaufman, who is Chief of the U.S. Attorney's Office Asset Forfeiture Unit, and Jennifer Caruso, a trial attorney from the Office of Chief Counsel for FDA.